



Express Mail No. EV 938 354 245 US

PATENT
Customer No. 23500

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Wei CHENG et al.

Serial No.: 10/569,873

Filed: September 4, 2007

For: C-KIT Modulators and Methods of Use

Confirmation No. 9736

Art Unit: 1626

Exr. Kristin Bianchi

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper is filed in response to the Restriction Requirement mailed February 9, 2009, in the above-referenced application.

In addition to this response, Applicants have submitted a request for a 1-month extension of time with the appropriate fee. It is believed that no additional fee is due in connection with this filing, but however, should a fee be due, the Commissioner is authorized to charge deposit account 50-1108 for the required amount.

The **Response** to the Restriction Requirement begins on page 2 of this paper.

RESPONSE TO RESTRICTION REQUIREMENT

In the Restriction Requirement which issued on February 9, 2009, the Examiner required the Applicants to elect one of the following groups:

Group I, claims 1-29, drawn to compounds, compositions and metabolites of Formulas I, II and III.

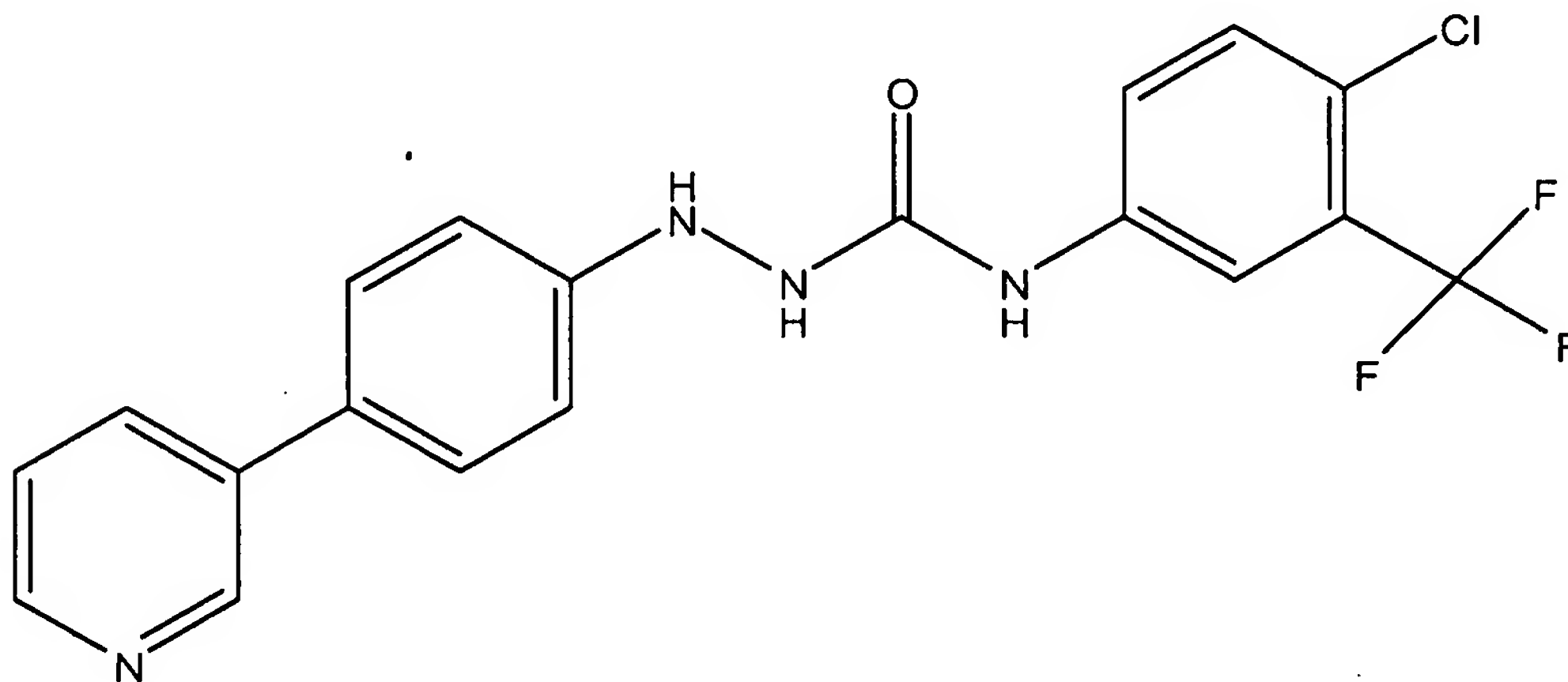
Group II, claims 30-33 and 35, drawn to methods which comprise administering a compound according to claim 1.

Group III, claim 34, drawn to a method for screening modulators of c-Kit.

In response to this Restriction Requirement, Applicants hereby provisionally elect, with traverse, **Group I**, claims 1-29, drawn to compounds, compositions and metabolites of Formulas I, II and III.

The Examiner also required the Applicants to elect a single species, selected from Formulae I, II and III in claim 27.

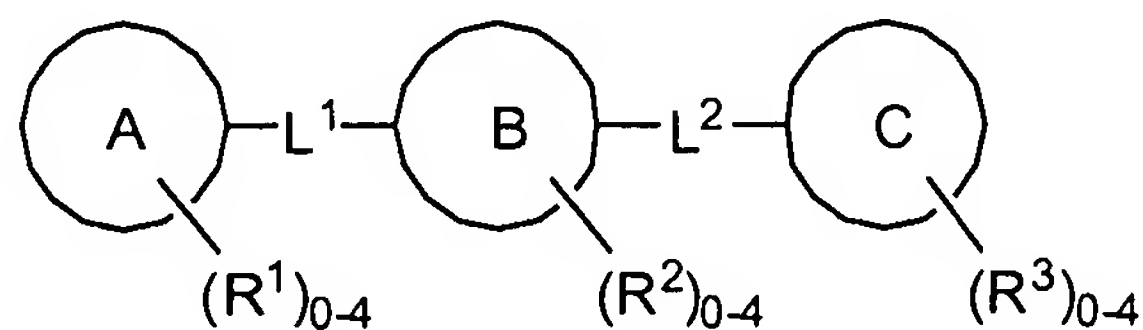
In response to this requirement, Applicants provisionally elect, with traverse, the following species which is disclosed as entry 120 in Table 1 of the specification as filed:



The claims that are readable on the provisionally elected species are claims 1-22 and 24-35.

Applicants respectfully traverse the election requirement for the following reasons:

Applicants' claimed compounds all share a common core structure of Formula I, as disclosed in the specification as filed, that have the same utility of modulating c-Kit.



The claims are written in Markush format. A Markush grouping is proper if the compounds in the Markush group share a single structural similarity and a community of properties (e.g., a common utility), such that the grouping is not repugnant to the principles of scientific classification. *Harnisch*, 206 U.S.P.Q. at 305; *Ex parte Brouard et al.*, 201 U.S.P.Q. 538, 540 (Bd. Pat. App. & Int. 1976). In other words, “unity of invention exists where compounds share a common utility, and (2) share a substantial structural feature essential to that utility.” M.P.E.P. § 802.03. The fact that the compounds in a Markush group may require different fields of search does not render the Markush group improper. *Brouard*, 201 U.S.P.Q. at 540. Also, where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by consideration of the compound as a whole, and does not depend on there being a community of properties among the members of the Markush expression. *Id*; *Harnisch*, 206 U.S.P.Q. at 305; M.P.E.P. § 2173.05(h). In *Harnisch*, 206 U.S.P.Q. at 305, and as it is applied in *Ex parte Hozumi*, 3 U.S.P.Q.2d 1059 (Bd. Pat. App. & Int. 1984), the determinative factor for determining whether or not a Markush group is proper was held to be whether there existed “unity of invention,” or rather whether the claims were drawn to a collection of unrelated inventions. Specifically, the claims in *Harnisch* were drawn to a class of substituted coumarin compounds disclosed as being “useful as dyestuffs.” 206 U.S.P.Q. at 305. Accordingly, all of the claims had in common a functional utility related to a substantial structural feature disclosed as being essential to that utility.

Applicants submit that each of the presently pending claims possesses unity of invention. All of the compounds share a common utility as modulators of c-Kit activity. Second, each of the compounds in the Markush groups of the claims share the following common core structure of formula I, as disclosed above and in the specification as filed, that is essential for the utility of inhibiting c-Kit.

Accordingly, all of the compounds read upon by the claims share structural features essential to the utility of these compounds as modulators of c-Kit activity.

Because the claims possess unity of invention, they are proper Markush claims and should be examined fully on their merits as generic linking claims for the elected group. To do otherwise would infringe on Applicants' "right to have each claim examined on the merits." *Weber*, 128 U.S.P.Q. at 331.

The proper procedure for examining Markush claims is provided in M.P.E.P. § 803.02:

A Markush-type claim may include independent and distinct inventions. ... In applications containing a Markush-type claim that encompasses at least two independent or distinct inventions, the examiner may require a provisional election of a single species prior to examination on the merits. ... Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

* * *

On the other hand, should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *nonelected species*, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The examination will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the


action can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

Applicants hereby preserve the right to prosecute the claims encompassed by any of the non-elected groups in future divisional applications.

If it is believed that a teleconference will advance prosecution, the Examiner is encouraged to contact the undersigned as indicated below.

Respectfully submitted,

Date: March 25, 2009


Robert L. Bernstein
Attorney for Applicants
Registration No. 46,020

Exelixis, Inc.
P.O. Box 511
249 East Grand Avenue
South San Francisco, CA 94083-0511
Telephone: 650-837-7352
Facsimile: 650-837-8234